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Zoom 307

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Leatrese J. HARRIS et al.

Serial No.: 09/939,714

Examiner: John M. Cooney

Filed: August 28, 2001

Group Art Unit: 1711

For: OPEN PORE BIODEGRADABLE MATRICES

#14 Req  
for refund  
05-21-03

**REQUEST FOR REFUND**

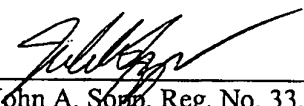
Assistant Commissioner for Patents  
Office of Finance  
Refund Section  
Box 16  
Washington, D.C. 20231

Sir:

Further to applicants filing of February 18, 2003, in the above identified application (a copy of which is attached hereto), Applicants hereby request a refund in the amount of \$465.00.

Applicants are entitled to small entity status and therefore, the correct fee is \$465.00. Therefore, it is respectfully requested that the difference, i.e., \$465.00, be refunded to counsel's Deposit Account No. 13-3402; two copies of this page are attached for this purpose.

Respectfully submitted,

  
\_\_\_\_\_  
John A. Sopp, Reg. No. 33,103  
Attorney for Applicants

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Attorney Docket No.: UMICH-4 C1

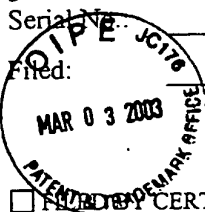
Filed: March 3, 2003

Serial No. 09/939,714

Docket No.: UMICH-4 C1

Filed: August 28, 2001

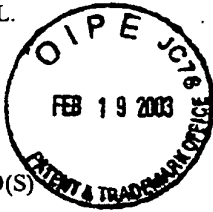
Applicant(s): Leatrese J. HARRIS et al.



THE U.S. PATENT AND TRADEMARK OFFICE STAMP HEREON  
ACKNOWLEDGES RECEIPT OF THE FOLLOWING PAPERS:

☐ RECEIVED BY CERTIFICATE OF MAILING ON:

- ☒ FEES \$ 930.00 Check No. 27162  
☐ MISSING PARTS RESPONSE W/DECL.  
☒ REPLY  
☐ RESPONSE ☐ ELECTION  
☐ NOTICE OF APPEAL  
☐ APPEAL BRIEF (TRIPPLICATE)  
☐ ASSIGNMENT  
☒ EXTENSION OF TIME 3 MO(S)  
☐ PRIORITY DOCUMENT(S)  
☐ VERIFIED STATEMENT(S) UNDER 37 C.F.R. 1.9 & 1.27  
☐ CONTINUATION PROSECUTION APPLICATION (CPA)



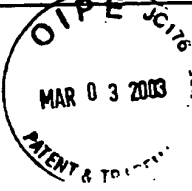
- ☐ STATEMENT OF USE  
☐ ISSUE FEE  
☐ DECLARATION UNDER  
☐ INFORMATION DISCLOSURE STATEMENT  
☐ PTO 1449 W/ REFS.  
☐ SHEETS OF DRAWINGS  
☐ COPY OF MISSING PARTS  
☐ RENEWAL APPLICATION  
☐ LETTER TO DRAFTSMAN  
☐ STATUS INQUIRY  
☐ APPLICATION DATA SHEET

OTHER: \_\_\_\_\_

Initials: JAS/slm

Date Filed: February 19, 2003 (2/17/03 Federal Holiday,  
2/18/03 Federal Gov't. Closed due to snow)

*Dkt'd 2/19/03-MR*

|   |                            |  |
|---|----------------------------|--|
| <b>PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)</b>                       |                            | Docket Number (Optional)<br>UMICH-4 C1 |
|  |                            |  |
| In re Application of Leatrese J. HARRIS et al.                                    |                            |  |
| Application Number 09/939,714   |                            | Filed August 28, 2001                  |
| For OPEN PORE BIODEGRADABLE MATRICES  |                            |  |
| Group Art Unit<br>1711  | Examiner<br>John M. Cooney |  |

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a response in the above identified application.

The requested extension and appropriate non-small-entity fee are as follows (check time period desired):

|  |                  |
|--|------------------|
| <input type="checkbox"/> One month (37 CFR 1.17(a)(1))               | \$ _____         |
| <input type="checkbox"/> Two months (37 CFR 1.17(a)(2))              | \$ _____         |
| <input checked="" type="checkbox"/> Three months (37 CFR 1.17(a)(3)) | \$ <u>930.00</u> |
| <input type="checkbox"/> Four months (37 CFR 1.17(a)(4))             | \$ _____         |
| <input type="checkbox"/> Five months (37 CFR 1.17(a)(5))             | \$ _____         |

☐ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee amount shown above is reduced by one-half, and the resulting fee is: \$ \_\_\_\_\_.

☒ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Commissioner has already been authorized to charge fees in this application to a Deposit Account.

☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 13-3402.

I have enclosed a duplicate copy of this sheet.

I am the ☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71

Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).


☒ attorney or agent of record.

☐ attorney or agent under 37 CFR 1.34(a).

Registration number if acting under 37 CFR 1.34(a). \_\_\_\_\_.

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

February 19, 2003  
\_\_\_\_\_  
Date

  
\_\_\_\_\_  
Signature

John A. Sopp, Reg. No. 33,103  
\_\_\_\_\_  
Typed or printed name

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☒ \*Total of 2 forms are submitted.

Burden Hour Statement: This form is estimated to take 0.1 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

COPY



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Leatrese J. HARRIS et al.

Serial No.: 09/939,714

Examiner: John M. Cooney

Filed: August 28, 2001

Group Art Unit: 1711

Title: OPEN PORE BIODEGRADABLE MATRICES

REPLY

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

In response to the Office Action mailed August 16, 2002, kindly reconsider the above-identified application for allowance in view of the following Remarks.

REMARKS

The Rejection under 35 U.S.C. § 103

The rejection of claims 1-36 under 35 U.S.C. § 103 as being obvious over Dorman (U.S. Patent No. 4,636,526) is respectfully traversed.

Dorman is directed to composite materials used for hard tissue prosthetics which contain synthetic biodegradable polymers and unsintered calcium phosphate material. The compositions are made in to a porous material by a particulate leaching method. Thus, the composite material is mixed with a pore-forming agent, such as a water soluble polymer or inert material, and then contacted with a solvent which dissolves and draws out the pore-forming agent to form pores; see, e.g., col. 2, line 63, to col. 3, line 6, and col. 7, lines 3-27.

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As admitted in the Office Action, Dorman teaches nothing regarding methods for forming additional pores in a particulate-leached material by gas foaming. Dorman, therefore, also cannot teach polymer materials which contain porosity resulting from both particulate leaching and of gas foaming.

The position apparently taken in the Office Action is that it was known in the art to form pores in a polymer material by gas foaming and, therefore, it would have been obvious to form pores by gas foaming in the Dorman materials, in addition to the porosity already formed therein by particulate leaching. No reference is cited to evidence such alleged obviousness of the gas foaming. On the record, the only suggestion for performing gas foaming together with particulate leaching comes from applicants' own disclosure, the use of which is improper to support a 35 U.S.C. § 103 rejection. This lack of evidence on the record, itself, is a convincing basis for withdrawal of the rejection. But the following additional reasons are provided for withdrawal of the rejection.

Even if the record did evidence art recognition of gas foaming to form porosity in polymers, it is a well established tenet of patent law that an invention directed to a combination of old elements is not obvious under 35 U.S.C. § 103 unless there is a suggestion in the art to combine those old elements. See, e.g., In re Fine, 5 USPQ 2d 1596,1598-99 (Fed. Cir. 1988), stating "[b]efore the PTO may combine the disclosures of two or more prior art references in order to establish prima facie obviousness, there must be some suggestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art." See also, In re Rouffet, 47 USPQ 2d 1453 (Fed. Cir. 1998), further discussing the need for motivation to combine art-known elements. Thus, even if it is assumed gas foaming of polymers to make them porous was known in the art, there is no suggestion from the prior art of record to combine a method of

forming porosity by particulate leaching (as in Dorman) and by gas foaming. The combination of porosity forming by each of the two methods provides materials with two types of porosity providing a novel pore structure. There is no suggestion from the art of a material which combines such or why such a combination of two types of porosity would be desired.

Dorman certainly provides no suggestion of conducting additional steps of gas foaming its materials to generate additional porosity therein. To the contrary, since Dorman is directed to materials for hard tissue prosthetics, such as bone, the initial direction to one of ordinary skill in the art would be to not form additional porosity because it would be expected to weaken the material. Also, there is certainly no suggestion from any art directed to gas foaming methods to combine such methods with particulate leaching methods for the simple reason that no art on gas foaming methods has been relied upon in the rejection. Thus, the only suggestion for combining the two types of porosity forming methods and provide a single material with both types of resulting porosity improperly comes from applicants' own disclosure. See, e.g., page 3, line 7, to page 5, line 15, describing the novel features of the invention and the advantages thereof not realized by the prior art.

It is urged that, in the absence of any suggestion in the art that it would have been desirable to modify a polymer having porosity from particulate leaching to provide additional porosity from gas foaming, the instant claims are not obvious. For this additional reason, no prima facie case of obviousness is supported and the rejection under 35 U.S.C. § 103 should be withdrawn.

The nonobviousness of certain dependent claims is even further evident. As to claims 25-26, 28-29 and 34-36, Dorman provides no teachings, whatsoever, suggesting incorporation of a drug or cells within its polymer material. As to claims 30-33, Dorman

provides no teaching or suggestion of connecting a portion of impermeable polymer with the porous materials. No references are cited to support obviousness of the additional recitations of these claims and no reasons are given as to why one of ordinary skill in the art would be motivated to modify Dorman to meet these aspects. Thus, there is additional basis for lack of a prima facie case of obviousness as to these claims.

Although such is unnecessary due to the absence of a prima facie case of obviousness, as discussed above, applicants do provide evidence in their specification showing the unexpected advantages of their invention. Thus, further supporting the nonobviousness thereof. On page 20 to page 21, the specification discusses the nature of the materials, as observed by photomicrographs, prepared by a combination of gas foaming and particulate leaching (GF/PL), according to applicants' invention, and those prepared by only gas foaming or only by particulate leaching (SC/PL), the latter as in Dorman. Gas foaming alone results in a largely closed pore structure and particulate leaching alone results in a non-uniform porosity. To the contrary, the GF/PL materials of applicants' invention exhibit a stable, uniform porosity with a significant open pore structure. Additionally, the GF/PL materials of applicants' invention and the SC/PL materials representative of Dorman were tested side-by-side for their mechanical properties. Applicants' materials exhibited significantly improved compressive and tensile modulus; see, e.g., Table I, page 22, and Figure 1. Examples 2-4 of applicants' specification show the further advantageous use of applicants' materials, particularly in the ability to incorporate and release growth factors due to their open porosity.


The above-discussed advantages of applicants' method and resulting polymers could not have been expected from the prior art cited in the Office Action. Thus, further proof of the nonobviousness of applicants' invention is provided.

For all of the above reasons, it is respectfully submitted that Dorman, considered as a whole, fails to render any of the instant claims obvious to one of ordinary skill in the art. Thus, the rejection under 35 U.S.C. § 103 should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

  
\_\_\_\_\_  
John A. Sopp, Reg. No. 33,103  
Attorney for Applicants

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Attorney Docket No.: UMICH-4 C1

Date: February 19, 2003

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